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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,737	07/31/2003	Marvin S. Antelman	10514-024-999	6939

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,737	ANTELMAN, MARVIN S.	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,258,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim methods of treating the same dermatological conditions with tetrasilver tetroxide. The US Patent claims that the method is free of added oxidizing agent which is defined by the Specification to include persulfate (US Pat. 6,258,385, Column 3, lines 15-27), as such, one of ordinary skill in the art would have been motivated to state that the method is free of persulfate. Futher, the methods of the U.S. Patent make obvious the composition claims of the application in that the methods disclose said compositions as indicated above.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of the US Patent to one of ordinary skill in the art at the time the invention was

made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-15,20,21,23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14,15,18-25 of US Patent 6,485,755. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim treatment of skin conditions with tetrasilver tetroxide. The US Patent claims that the method is substantially free of added persulfate (US Pat. 6,485,755, Claim 15), as such, one of ordinary skill in the art would have been motivated to state that the method is free of persulfate. Futher, the methods of the U.S. Patent make obvious the composition claims of the application in that the methods disclose said compositions as indicated above.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of the US Patent to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the tetrasilver tetroxide, does not reasonably provide enablement for all pharmaceutically acceptable derivatives or treatment, prevention or managment of all conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to preventing, treating or managing one or more dermatological skin diseases in a patient's skin with tetrasilver tetroxide, or a pharmaceutically acceptable derivative, thereof, which is substantially free of added persulfate.

The state of the prior art and the predictability or lack thereof in the art:

Although the prior art of record shows the effectiveness of silver and tetrasilver tetroxide as an antimicrobial agent, the prior art of record does not appear to show that the silver or tetrasilver tetroxide is capable of treating,managing or preventing the enumerable possible dermatological skin disease which would fall within the scope of claims

The amount of direction or guidance present and the presence or absence of working examples:

The Specification provides methods of administration and amounts but relatively few examples of effective treatment of a few dermatological conditions with tetrasilver tetroxide and does not appear to show prevention of any dermatological disease or condition or what derivatives of tetrasilver tetroxide would be suitable.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim undefined derivatives of tetrasilver tetroxide and any dermatological skin disease. As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to determine what other disease conditions would be effectively treated or managed, to determine that the dermatological skin diseases could be prevented and what derivatives would be effective for treatment, management or prevention of the dermatological skin diseases.erivatives of tetrasilver tetroxide or working examples showin their effectiveness.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-24 contain the limitation "pharmaceutically acceptable derivative" which renders the claims indefinite as it is uncertain what is and what is included within the scope of said term and the Specification does not appear to adequately provide direction as to the same.

Claim Rejections - 35 USC § 102/103

Examiner notes that the rejections under this section herein are not applicable to subject matter which was allowed in U.S. 6,258,385.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7, 8, 9, 3, 14, 17, 20, 22 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Antelman (U.S. Pat, 5,571,520).

Antelman expressly discloses a method of treating athlete's foot and toenail fungus with solutions of tetrasilver tetroxide falling within the scope of applicant's claims (Column 4, lines 25-36). Athlete's foot and/or toenail fungus is associated with skin chafing, skin cracking, skin itch, and skin peeling.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1-24 are rejected under 35 U.S.C. 103(a) as obvious over Antelman (U.S. Pat. No. 5,571,520) in view of the acknowledge prior art, De Cuellar et al. (US Pat. 4,828,832), Fox, Jr., et al. (US Pat. 5,334,588), Dorland's (28th Ed. 1994), The Merck Manual (16th Ed. 1992), and Remington's (17th Ed. 1985).

Antelman teaches methods of treating dermatological conditions or diseases containing a molecular crystal device which is effective against bacteria, fungi, viruses and algae (Column 1,

lines 44-47, Column 2, lines 38-68, Column 3, lines 1-20, Column 4, lines 25-36). It is taught that said device consists of a single crystal of tetrasilver tetroxide and that several hundred thousand trillion of these devices may be employed in concert for their bactericidal, fungicidal and algicidal properties and in various pharmaceutical formulations and therapies (Column 1, lines 44-52). A dermatological cream and douche containing 10 PPM, a solution containing 100 PPM, and a suspension of 25%, of said devices are taught (Column 2, lines 64-68, Column 3, lines 12-14, Column 4, lines 28, 29, 34). It is taught that amount of said devices contained in the formulations was determined by the minimal concentration of tetrasilver tetroxide required to inhibit the microorganism in nutrient broth (Column 2, lines 39-44).

Applicant acknowledges that it is known that tetrasilver tetroxide is effective against a wide spectrum of pathogens, including bacteria, algae, mold and the AIDS virus (Pg. 3, lines 22-36, Pg. 4).

De Cuellar et al. teach that silver oxide is effective against, pressure ulcers, chafing, impetigo, furunculosis sycosis of the beard, infected eczematous dermatitis, purulent acne, and postulous psoriasis, and that silver oxide compound avoids the side effects of silver sulfadizine therapy (Column 1, lines 50-68, Column 2, lines 1, 2, Column 3, lines 3-17, Column 4, lines 15-47).

Fox, Jr., et al. teach that silver compounds are effective against herpes simplex and herpes zoster and that silver oxide may be used in place of silver sulfadiazine (Column 2, lines 33-44, Column 3, lines 26-28, 31, 32).

Dorland's teaches that cold sores are caused by herpes simplex virus type1 and that shingles is caused by herpes zoster (Pgs. 351, 759-60).

The Merck Manual teaches that warts are caused by viruses (Pgs. 2426-27).

Remington's teaches that water-washable bases or emulsion bases, commonly referred to as creams, represent the most commonly used type of ointment bases and that emulsions bases are washable and easily removed from skin or clothing (Pg. 1574). It is taught that the oil phase of the emulsion base is typically contains petrolatum (Pg. 1574). It is taught that powders are encountered in almost every aspect of pharmacy, both in industry and in practice (Pg. 1585) Various methods of producing powders are taught, including bulk powders, such as douche powders and dusting powders (Pgs. 1585-1594, 1601). A method is taught of preparing dilutions of potent powdered drugs wherein the drug is intimately mixed with a suitable diluent (Pgs 1601, 1602).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the formulation of tetrasilver tetroxide dispersed in a petroleum jelly base or as a powder, and methods of treating eczema, psorisasis,dermatitis,ulcers, shingles, rashes, bedsores, cold sores, blisters, boils, herpes, acne, pimples and warts with tetrasilver tetroxide. However, the prior art amply suggests the same as methods of preparing formulations, such as powders and creams, containing drugs, are well known in the art, and methods of treating dermatological conditions or diseases containing tetrasilver tetroxide are known in the art (Antelman, Column 1, lines 44-52, Column 2, lines 38-68, Column 3, lines 1-20, Column 4, lines 25-36; Specification, Pg. 1, lines 21-24; Remington's, Pgs. 1574, 1585-94, 1601, 1602). Furthermore, the prior art teaches equivalents, active ingredients, amounts and/or method steps which are close enough, overlap or are within the range and specific limitations of the claimed invention such that one of ordinary skill in the art would expect them to have the same properties (Antelman, Column 1, lines 44-52, Column 2, lines 38-68, Column 3, lines 1-20, Column 4, lines 25-36; Specification, Pg. 1, lines 21-24; De Cuellar et al., Column 1, lines 50-68, Column 2,

lines 1, 2, Column 3, lines 3-17, Column 4, line 33; Fox, Jr., et al., Column 2, lines 33-44, Column 3, lines 26-28, 31, 32; Dorland's, Pgs. 351, 759-60, Remington's, Pgs. 1574, 1585-94, 1601, 1602). As such, it would have been well within the skill of one of ordinary skill in the art to employ various amounts of the active ingredients and method steps depending on end utility including amounts and method steps that fall within the scope of the claimed invention, because the same found in the prior art are fairly encompassed by or are close to the range and specific limitations of the claimed invention. Also, it would have been well within the skill of one of ordinary skill in the art arrive at the various amounts and/or ranges of tetrasilver tetroxide by optimization of the prior art conditions (Antelman, Column 2, lines 39-44). It would have been well within the skill of and one of ordinary skill in the art would have been motivated to treat cold sores, herpes, shingles and acne by applying tetrasilver tetroxide with the expectation that tetrasilver tetroxide would be effective as silver compounds, including silver oxide, are known to be effective in treating acne, herpes zoster and herpes simplex, and that warts are caused by viruses, therefore, it would have been expected that tetrasilver tetroxide, which is known to be a broad spectrum biocide, would also be effective (De Cuellar et al., Column 1, lines 50-68, Column 2, lines 1, 2, Column 3, lines 3-17, Column 4, line 33; Fox, Jr., et al., Column 2, lines 33-44, Column 3, lines 26-28, 31, 32; Dorland's, Pgs. 351, 759-60; The Merck Index, pg. 2426-27). Also, one of ordinary skill in the art would have been motivated to employ a silver oxide compound, i.e. tetrasilver tetroxide, instead of silver sulfadiazine as tetrasilver tetroxide would be expected to have less side effects (De Cuellar et al., Column 1, lines 50-68, Column 2, lines 1, 2). Further, one of ordinary skill in the art would have been motivated to modify the prior art as above so as to employ a pharmaceutical formulation which is effective against a wide variety of dermatological pathogens and utilizes common industrial/pharmaceutical methods of preparing powders and creams (Antelman, Column 1, lines 44-52, Column 2, lines 38-68, Column 3,

lines 1-20, Column 4, lines 25-36; Specification, Pg. 1, lines 21-24; De Cuellar et al., Column 1, lines 50-68, Column 2, lines 1, 2, Column 3, lines 3-17, Column 4, line 33; Fox, Jr., et al., Column 2, lines 33-44, Column 3, lines 26-28, 31, 32; Dorland's, Pgs. 351, 759-60; The Merck Index, pgs. 2426-37; Remington's, Pgs. 1574, 1585-94, 1601, 1602).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached at (571)272-0602). Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

March 8, 2004

S. MARK CLARDY
PATENT EXAMINER
GROUP 1600
1616